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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,527	03/08/2000	Didier Leturcq	ORT1199	1068

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/521,527

Applicant(s)

Leturcq, D.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/13/01, 2/12/02, 6/17/02, and 2/06/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 10-12, and 14-16 is/are pending in the application.
- 4a) Of the above, claim(s) 8, 10-12, and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. Applicant's amendments, filed 7/13/01, 2/12/02, and 6/17/02, are acknowledged. In view of Applicant's appropriate assurances regarding the deposits of the hybridomas designated by ATCC™ Accession Nos. HB-12441 or HB-12657, the previous rejection under the first paragraph of 35 U.S.C. 112 have been withdrawn.

2. Applicant's election of Group I, Claims 1-6, with traverse, in Paper No. 24, filed 2/06/03, is acknowledged.

Applicant argues that examination has begun without a restriction requirement, thus the Examiner felt that an examination did not require a restriction.

It is noted that the arguments do not indicate that restriction was improper, only that examination had begun. Applicant is advised that each restriction and examination is made by the Examiner of record within the framework of rules set forth in the MPEP. As there is no argument that restriction is actually improper, the restriction is deemed proper and is therefore made FINAL.

3. Claims 8, 10-12, and 14-16 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-6 are being acted upon.

4. The specification is objected to for the following informalities:

A) The use of the trademark "ATCC" has been noted in this application. It should be capitalized and accompanied by the ™ symbol in all instances where it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. Claim 2 is objected to as being of identical scope as Claim 1.

6. The following are new grounds for rejection.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) Claim 4 contains the trademark ATCC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify American Type Culture Collection and, accordingly, the identification is indefinite.

B) Claim 6 is grammatically incorrect in the recitation of "...the polypeptide designated CD-83 and having..." Applicant is advised that the deletion of "and" would obviate the rejection.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:
a method of isolating human CD8+ cells comprising the formation of a first complex between the whole antibodies produced by the hybridomas designated by ATCC™ Accession Nos. HB-12441 or HB-12657 and SEQ ID NO:1,
does not reasonably provide enablement for:

a method of isolating human CD8+ cells comprising the formation of a first complex between the antibodies which bind SEQ ID NO:1 or portions thereof.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

Regarding "antibodies", the specification defines the term as encompassing "fragments thereof" at page 7, line 20. "Fragments thereof" would comprise any and all possible fragments including single amino acids. It is well-known in the art that very short peptide fragments or single amino acids would not likely bind other peptide sequences, thus the claimed invention must be considered to be highly unpredictable given the breadth of the claims. Given said unpredictability, the invention is considered to require undue experimentation to practice as claimed.

Regarding a "portion" of the sequence of SEQ ID NO:1, the specification provides no guidance as to which portions can be bound by an antibody and which cannot. Again, given the breadth of the claims, sequences as short as a single amino acid would be encompassed. It is well-known in the immunological arts that the absolute minimum length of a sequence to which an antibody can bind is about 5 amino acids. Accordingly, the claimed invention must be considered to be highly unpredictable given said breadth. Given said unpredictability, the invention is considered to require undue experimentation to practice as claimed.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples encompassing the breadth of the claimed invention, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

11. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the "first antibody", other than the antibody produced by the hybridoma designated by ATCCTM Accession Nos. HB-12441 or HB-12657, recited in the claims. As set forth above, the term encompasses fragments of antibodies that bind SEQ ID NO:1, however, no such fragments are disclosed. As the term would potentially encompass an essentially unlimited genus, one of skill in the art would conclude that the specification fails to adequately describe the "antibody" required for use in the claimed method. Likewise, there is insufficient written description to show that Applicant was in possession of the "portion" of SEQ ID NO:1 bound by said "first antibody". Again, as the term would potentially encompass an essentially unlimited and undisclosed genus, one of skill in the art would conclude that the specification fails to adequately describe the "portion" of SEQ ID NO:1 required for use in the claimed method. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).

A handwritten signature in black ink, appearing to read 'G.R. Ewoldt', with a stylized flourish at the end.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
April 18, 2003